Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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Report Date:10/04/2007

# **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest	059601105 058800405 059700601 058800603 059700805 059600105	06/04/01 09/13/99 05/25/00 08/06/01 10/01/01 01/18/99	729 729 726 729 729 729	50 (5) 50 (5) 50 (5) 50 (5) 49 (5) 50 (5)	26(676) 31(686) 32(693) 27(680) 27(683) 29(701)	540.9 519.5 529.7 537.2 525.0 534.2	Cumene Divinylbenzene Methyl isobutyl ketone alpha-Methylstyrene Propargyl alcohol Stoddard solvent (type IIC)
				Fen	nale		
Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest	059601105 058800405 059700601 058800603 059700805 059600105	06/04/01 09/13/99 05/25/00 08/06/01 10/01/01 01/18/99	731 731 727 730 730 730	50 (5) 50 (5) 50 (5) 50 (5) 50 (5) 50 (5)	21(674) 33(679) 35(694) 27(647) 29(678) 36(696)	356.9 355.3 365.6 351.9 353.3 363.6	Cumene Divinylbenzene Methyl isobutyl ketone alpha-Methylstyrene Propargyl alcohol Stoddard solvent (type IIC)

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
All Organs: Benign Tumors								
· ·		48/50 (96%)	49/50 (98%)	50/50 (100%)		44/50 (88%)	43/50 (86%)	44/50 (88%)
		48/50 (96%)	48/49 (98%)	50/50 (100%)		43/50 (86%)	42/50 (84%)	37/50 (74%)
verall Incidence	Total	293/299 (97.99%)	Mean 97.99%	SD 1.79%	Total	253/300 (84.33%)	Mean 84.33%	SD 5.28%
All Organs: Malignant Tumors								
		36/50 (72%)	29/50 (58%)	31/50 (62%)		24/50 (48%)	17/50 (34%)	22/50 (44%)
	<b>-</b>	32/50 (64%)	32/49 (65%)	33/50 (66%)	<b>-</b>	25/50 (50%)	26/50 (52%)	30/50 (60%)
Overall Incidence	Total	193/299 (64.55%)	Mean 64.55%	SD 4.65%	Total	144/300 (48%)	Mean 48%	SD 8.67%
#All Organs: Malignant and Benign T	umors	E0/E0 (4052)	50/50 (400s)	F0/F0 (4000)		F0/F0 (4003)	40/50 (000/)	40/50 (005)
		50/50 (100%) 50/50 (100%)	50/50 (100%) 49/49 (100%)	50/50 (100%) 50/50 (100%)		50/50 (100%) 46/50 (92%)	46/50 (92%) 47/50 (94%)	46/50 (92%) 44/50 (88%)
Overall Incidence	Total	299/299 (100%)	Mean 100%	50/50 (100%) SD 0%	Total	279/300 (93%)	Mean 93%	SD 3.95%
fAll Organs:								
Hemangioma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#All Organs: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overell Incidence	Total	0/50 (0%)	0/49 (0%)	0/50 (0%)	Total	0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#All Organs: Hemangiosarcoma or Hem	angioma	0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/299 (0.33%)	0/49 (0%) ( Mean 0.33%	0/50 (0%) SD 0.82%	Total	1/50 (2%) 3/300 (1%)	2/50 (4%) Mean 1%	0/50 (0%) SD 1.67%
#All Organs: Histiocytic Sarcoma							•••••	
riistiocytic Jarconia		0/50 (0%)		0/50 (0%)		0/50 (0%)	2/50 (4%)	2/50 (4%)
Overall Incidence	Total	1/50 (2%) 2/299 (0.67%)	0/49 (0%) ( Mean 0.67%	0/50 (0%) SD 1.03%	Total	0/50 (0%) 4/300 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.07%
Overall incluence	TOLAI	2/299 (0.07%)				4/300 (1.33%)		
#All Organs: Leukemia: Lymphocytic, N Undifferentiated	lonocytic, N	26/50 (52%)		25/50 (50%)		12/50 (24%)	10/50 (20%)	14/50 (28%)
Overall Incidence	Total	26/50 (52%) 145/299 (48.49%)	21/49 (43%) 2 Mean 48.48%	25/50 (50%) SD 4.03%	Total	18/50 (36%) 100/300 (33.33%)	20/50 (40%) Mean 33.33%	26/50 (52%) SD 11.78%
#All Organs: Malignant Lymphoma: His or Undifferentiated Cell Ty		nphocytic, Mixed, NOS,	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/299 (0%)	0/49 (0%) ( Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#All Organs: Mesothelioma: Benign	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
• " " " " " " " " " " " " " " " " " " "	<b>.</b>	0/50 (0%)	0/49 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male		Female	
#All Organs: Mesothelioma: Benign,	, Malignant, NO	 S				
		3/50 (6%)	2/50 (4%) 1/50	(2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 7/299 (2.34%)	1/49 (2%) 0/50 Mean 2.34% SD	(0%) 2.34% Total	0/50 (0%) 1/50 (2%) 1/300 (0.33%) Mean 0.33%	0/50 (0%) SD 0.82%
#All Organs:						
Mesothelioma: Maligna	ınt					
		3/50 (6%)	2/50 (4%) 1/50	(2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 7/299 (2.34%)	1/49 (2%) 0/50 Mean 2.34% SD	(0%) 2.34% Total	0/50 (0%) 0/50 (0%) 0/300 (0%) Mean 0%	0/50 (0%) SD 0%
		,			0/300 (0%) Weath 0%	
#All Organs: Osteoma						
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0% SD		0/300 (0%) Mean 0%	SD 0%
#All Organs: Osteosarcoma						
001000011001110		0/50 (0%)	1/50 (2%) 0/50	(0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%) 2/50	(4%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/299 (1.34%)	Mean 1.34% SD	1.64% Total	1/300 (0.33%) Mean 0.33%	SD 0.82%
#All Organs: Osteosarcoma or Oste						
	<del>-</del> <del></del>	0/50 (0%)	1/50 (2%) 0/50	(0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
	_	0/50 (0%)	1/49 (2%) 2/50	(4%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/299 (1.34%)	Mean 1.34% SD	1.64% Total	1/300 (0.33%) Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Adrenal Cortex: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/299 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	2/50 (4%) 2/300 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.63%
Adrenal Cortex:								
Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/299 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	1/50 (2%) SD 0.82%
		` ,				` ,		
Adrenal Medulla: Ganglioneuroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Normall In aideana	Tatal	0/50 (0%)	0/49 (0%)	0/50 (0%)	Tatal	0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Hemangioma							•••••	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
No. 10 10 10 10 10 10 10 10 10 10 10 10 10	T-1-1	0/50 (0%)	0/49 (0%)	0/50 (0%)	T-1-1	0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma Benign	•••••				•••••			
i neocinomocytoma Berngii		7/50 (14%)	12/50 (24%)	8/50 (16%)		1/50 (2%)	2/50 (4%)	3/50 (6%)
		8/50 (16%)	8/49 (16%)	5/50 (10%)		1/49 (2%)	1/50 (2%)	2/50 (4%)
Overall Incidence	Total	48/299 (16.05%)	Mean 16.05%	SD 4.56%	Total	10/299 (3.34%)	Mean 3.34%	SD 1.63%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Adrenal Medulla: Pheochromocytoma Co	omplex							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/5 0/49 (0%) 0/5	` '		1/50 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	` '	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
*Adrenal Medulla:								•••••
Pheochromocytoma Ma	alignant	1/50 (2%) 2/50 (4%)	1/50 (2%) 0/5 3/49 (6%) 1/5	` '		1/50 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	8/299 (2.68%)	` '	SD 2.11%	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%
*Adrenal Medulla: Pheochromocytoma: B		x, <b>Malignant, NOS</b> 7/50 (14%) 10/50 (20%)	13/50 (26%) 8/5 10/49 (20%) 6/5	50 (16%) 50 (12%)		3/50 (6%) 1/49 (2%)	2/50 (4%) 1/50 (2%)	3/50 (6%) 3/50 (6%)
Overall Incidence	Total	54/299 (18.06%)	Mean 18.07%	SD 5.09%	Total	13/299 (4.35%)	Mean 4.34%	SD 1.96%
#Blood Vessel: Osteosarcoma								
		0/50 (0%)	0/50 (0%) 0/5			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/299 (0%)	0/49 (0%) 0/5 Mean 0%	50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Chondrosarcoma								
Gilonal Osai Coma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/5 0/49 (0%) 0/5	` '		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	` '	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male		Female
Bone: Chondrosarcoma or Chondro	oma				
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
	<b>-</b>	0/50 (0%)	0/49 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0% SD (		0/300 (0%) Mean 0% SD 0%
Bone: Chordoma					
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	1/49 (2%) 0/50	(0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34% SD (	0.83% Total	0/300 (0%) Mean 0% SD 0%
Bone: Osteoma				•••••	
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/49 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0% SD (		0/300 (0%) Mean 0% SD 0%
Bone: Osteosarcoma					
Osteosarcoma		0/50 (0%)	1/50 (2%) 0/50	(0%)	1/50 (2%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	1/49 (2%) 2/50	(4%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	4/299 (1.34%)	Mean 1.34% SD	I.64% Total	1/300 (0.33%) Mean 0.33% SD 0.82%
Bone: Osteosarcoma or Osteoma	•••••				
		0/50 (0%)	1/50 (2%) 0/50	(0%)	1/50 (2%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	1/49 (2%) 2/50	(4%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	4/299 (1.34%)	Mean 1.34% SD	I.64% Total	1/300 (0.33%) Mean 0.33% SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Brain: Astrocytoma Malignant								
-		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>.</b>	0/50 (0%)	0/49 (0%)	1/50 (2%)	<b>+</b>	1/50 (2%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Brain: Ependymoma Benign								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Brain: Glioma Malignant				•••••		•••••	•••••	
-		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%
Brain: Granular Cell Tumor Benign				•••••	•••••	•••••		
Granaia. Con ramor Zomgn		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Brain: Medulloblastoma Mal								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%)	0/49 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/299 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Brain:								
Meningioma Malignant		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/30 (0%)
verall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Brain:								•••••
Meningioma: Benign, Ma	lignant, NOS							
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Suranall In alidamaa	Tatal	0/50 (0%)	0/49 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Beni	an							
ongodonarognoma zom	9	0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Brain:	•••••							
Oligodendroglioma Malig	gnant	0/50 (00/)	0/40 (00/)	0/50 (00/)		4/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)
verall Incidence	Total	0/50 (0%) 0/298 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	()	0/50 (0%) Mean 0.33%	0/49 (0%) SD 0.82%
verali ilicidence		, ,				,	iviean 0.33%	SD 0.62%
Brain:								
Oligodendroglioma, Glio	ma, or Astroc		0/49 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		2/50 (4%) 2/50 (4%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%	Total	4/299 (1.34%)	Mean 1.33%	SD 2.07%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS

Strain: F344

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Clitoral/Preputial Gland: Adenoma								
		0/50 (0%)	0/48 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	3/49 (6%)	0/50 (0%)		0/50 (0%)	4/50 (8%)	0/49 (0%)
verall Incidence	Total	3/297 (1.01%)	Mean 1.02%	SD 2.5%	Total	5/299 (1.67%)	Mean 1.67%	SD 3.2%
Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%)	0/48 (0%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	1/50 (2%)
		2/50 (4%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	3/297 (1.01%)	Mean 1%	SD 1.67%	Total	5/299 (1.67%)	Mean 1.67%	SD 1.51%
Clitoral/Preputial Gland: Carcinoma or Adenoma			•••••	•••••				•••••
		0/50 (0%)	0/48 (0%)	1/50 (2%)		3/50 (6%)	0/50 (0%)	1/50 (2%)
		2/50 (4%)	3/49 (6%)	0/50 (0%)		1/50 (2%)	4/50 (8%)	1/49 (2%)
Overall Incidence	Total	6/297 (2.02%)	Mean 2.02%	SD 2.57%	Total	10/299 (3.34%)	Mean 3.34%	SD 3.01%
Clitoral/Preputial Gland: Fibrosarcoma			•••••	•••••				•••••
		0/50 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Clitoral/Preputial Gland: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%)	0/48 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/50 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Ear: Neural Crest Tumor								
Nediai Crest Tullio		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/300 (0%)	Mean 0%	SD 0%
Esophagus: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Sec	T-1-1	0/50 (0%)	0/49 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
≇Eye: Amelanotic Melanoma, Beι	nign							
,	J	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
≠Eye: Melanoma Benign								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
≇Eye: Schwannoma Malignant					•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/49 (0%)	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
Overali incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Harderian Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
N	T-1-1	0/50 (0%)	0/49 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Harderian Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>-</b>	0/50 (0%)	0/49 (0%)	0/50 (0%)	<b>.</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Harderian Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Benign								
3		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/299 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/299 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

#### **Toxicology Data Management System**

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0/50

0/50

0/50

0/300

Total

(0%)

(0%)

(0%)

(0%)

Mean 0%

0/50

0/50

SD 0%

(0%)

(0%)

Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups

**Route: INHALATION** Vehicle: AIR

Male Female #Intestine Large: Colon/Rectum: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) (0%) 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 0/50 Mean 0% **Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% 0/300 (0%) SD 0% Total #Intestine Large: Colon/Rectum: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% 0/300 (0%) Mean 0% SD 0% Total ...... #Intestine Large: Colon/Rectum: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** SD 0% SD 0% Total 0/299 (0%) Mean 0% Total 0/300 (0%) Mean 0% #Intestine Large: Colon/Rectum: Leiomyosarcoma (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/299 (0%) SD 0% SD 0% Total Mean 0% Total 0/300 (0%) Mean 0% #Intestine Small: Duodenum: Carcinoma

0/50

0/50

SD 0%

.....

(0%)

(0%)

Total

0/50

0/50

0/299

(0%)

(0%)

(0%)

0/50

0/49

(0%)

(0%)

Mean 0%

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: F344

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Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Intestine Small: Duodenum: Leiomyoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
S U. I	T-1-1	0/50 (0%)	0/49 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Leiomyoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overell Incidence	Tatal	0/50 (0%)	0/49 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Hntestine Small: Site Unspecifi Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unspecifi Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>.</b>	0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

**Route: INHALATION** Vehicle: AIR

Length of Study: CHRONIC

Male Female #Intestine Small: Site Unspecified: Leiomyoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%) 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 0/50 Mean 0% Overall Incidence Total 0/299 (0%) Mean 0% SD 0% 0/300 (0%) SD 0% Total #Intestine Small: Site Unspecified: Leiomyosarcoma 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/300 (0%) Mean 0% SD 0% 0/299 (0%) Total \*Islets, Pancreatic: Adenoma (6%) 1/50 (10%)1/50 (2%)1/50 (2%)(0%)3/50 (6%)(8%) 3/50 (6%)3/50 (6%)1/50 (2%) 1/49 (2%) **Overall Incidence** SD 2.68% SD 1.97% Total 19/299 (6.35%)Mean 6.36% Total 7/299 (2.34%) Mean 2.34% \*Islets, Pancreatic: Carcinoma (0%)2/50 (4%)1/50 (2%)4/50 (8%)1/50 0/50 (0%)0/50 1/50 (2%)5/49 (10%)1/50 (2%)0/50 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** 14/299 SD 3.56% (0.33%)SD 0.82% Total (4.68%)Mean 4.7% Total 1/299 Mean 0.33% \*Islets, Pancreatic: Carcinoma or Adenoma (14%)3/50 (6%)6/50 (12%)2/50 (0%)4/50 (8%)(18%)4/50 (8%)3/50 (6%)1/50 (2%)1/49 (2%)**Overall Incidence** Total 33/299 (11.04%)Mean 11.06% SD 4.63% Total 8/299 (2.68%)Mean 2.67% SD 2.06% .....

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

1: Oct2007

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Kidney: Pelvis and Transi Carcinoma	itional Epitheliu	m:						
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/298 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Transi Carcinoma or Adenom	tional Epitheliu							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/298 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Transi Papilloma		m:	•••••					
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Adenoma			•••••	•••••		•••••		
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/298 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/298 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 130

			Male				Female	
Kidney: Renal Tubule: Carcinoma or Adenoma								
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>-</b>	0/50 (0%)	0/49 (0%)	1/50 (2%)	<b>-</b>	0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	3/299 (1%)	Mean 1%	SD 1.67%	Total	0/298 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>-</b>	0/50 (0%)	0/49 (0%)	0/50 (0%)	<b>-</b>	0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Lipoma				•••••				
·		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/298 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Liposarcoma			•••••	•••••			•••••	
·		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/298 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Mesenchymal Tumor Beniç								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Normall Institutes	Tatal	0/50 (0%)	0/49 (0%)	0/50 (0%)	Tatal	0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Kidney: Renal Tubule: Nephroblastoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>-</b>	0/50 (0%)	0/49 (0%)	0/50 (0%)	<b>.</b>	0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%
Liver: Cholangiocarcinoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
_iver: Cholangioma						•••••		
<b>-</b>		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Liver: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Liver: Hepatocellular Adenoma								
ricpatocenalai Adenoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/299 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Carcinom	a							
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/299 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Carcinom	a or Hepatobl	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/299 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Carcinom	a or Hepatoce	ellular Adenoma 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/49 (2%)	1/50 (2%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.04%	Total	0/299 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Carcinom Hepatoblastoma	a, Hepatocell	ular Adenoma, or						
- I.		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Nevell Incidence	Total	0/50 (0%)	1/49 (2%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.04%	Total	0/299 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Lung: Alveolar/Bronchiolar A	denoma							
Aiveolai/biolicillolai A	idenoma .	1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	1/49 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	3/299 (1%)	Mean 1.01%	SD 1.1%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Lung: Alveolar/Bronchiolar C	Carcinoma							
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/49 (0%)
verall Incidence	Total	3/299 (1%)	Mean 1%	SD 1.1%	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%
Lung: Alveolar/Bronchiolar C Adenoma	Carcinoma or Al							
		2/50 (4%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/50 (0%)	1/49 (2%) Mean 2.01%	2/50 (4%) SD 1.79%	Total	0/50 (0%)	1/50 (2%) Mean 1%	0/49 (0%) SD 1.1%
	Total	6/299 (2.01%)	wean 2.01%	30 1.79%	ı olal	3/299 (1%)		
Lung: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>T</b>	0/50 (0%)	0/49 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Lung: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 134

			Male	Female
Lung: Squamous Cell Carcinoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		1/50 (2%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%)
verall Incidence	Total	1/299 (0.33%)	Mean 0.33% SD 0.82%	Total 0/299 (0%) Mean 0% SD 0%
Lymph Node, Mesenteric: Sarcoma				
		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33% SD 0.82%	Total 0/300 (0%) Mean 0% SD 0%
Mammary Gland: Adenoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	2/49 (4%) 0/50 (0%)	0/50 (0%) 3/50 (6%) 0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.68% SD 1.67%	Total 3/300 (1%) Mean 1% SD 2.45%
Mammary Gland: Carcinoma				
		2/50 (4%)	1/50 (2%) 2/50 (4%)	10/50 (20%) 3/50 (6%) 5/50 (10%)
		0/50 (0%)	0/49 (0%) 0/50 (0%)	3/50 (6%) 7/50 (14%) 4/50 (8%)
verall Incidence	Total	5/299 (1.67%)	Mean 1.67% SD 1.97%	Total 32/300 (10.67%) Mean 10.67% SD 5.47%
Mammary Gland: Carcinoma or Adenoma				
		2/50 (4%)	1/50 (2%) 2/50 (4%)	10/50 (20%) 3/50 (6%) 5/50 (10%)
		0/50 (0%)	2/49 (4%) 0/50 (0%)	3/50 (6%) 10/50 (20%) 4/50 (8%)
Overall Incidence	Total	7/299 (2.34%)	Mean 2.35% SD 1.98%	Total 35/300 (11.67%) Mean 11.67% SD 6.62%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Mammary Gland: Fibroadenoma								
		0/50 (0%)	1/50 (2%)	2/50 (4%)		24/50 (48%)	20/50 (40%)	22/50 (44%)
		1/50 (2%)	1/49 (2%)	3/50 (6%)		22/50 (44%)	26/50 (52%)	19/50 (38%)
verall Incidence	Total	8/299 (2.68%)	Mean 2.67%	SD 2.06%	Total	133/300 (44.33%)	Mean 44.33%	SD 5.13%
Mammary Gland: Fibroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenor	ma or Adenoma							
		0/50 (0%)	1/50 (2%)	2/50 (4%)		24/50 (48%)	20/50 (40%)	22/50 (44%)
	<b></b>	1/50 (2%)	3/49 (6%)	3/50 (6%)	<b>.</b>	22/50 (44%)	28/50 (56%)	19/50 (38%)
verall Incidence	Total	10/299 (3.34%)	Mean 3.35%	SD 2.45%	Total	135/300 (45%)	Mean 45%	SD 6.42%
Mammary Gland: Fibroma, Fibroadenor	ma Carcinoma o	or Adenoma						
r ibroma, r ibroadonor	ma, caromoma, c	2/50 (4%)	1/50 (2%)	4/50 (8%)		31/50 (62%)	22/50 (44%)	26/50 (52%)
		1/50 (2%)	3/49 (6%)	3/50 (6%)		24/50 (48%)	31/50 (62%)	23/50 (46%)
verall Incidence	Total	14/299 (4.68%)	Mean 4.69%	SD 2.44%	Total	157/300 (52.33%)	Mean 52.33%	SD 7.94%
Mesentery: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Mesentery: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	T-1-1	0/50 (0%)	0/49 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Mesentery: Osteosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	T-1-1	0/50 (0%)	0/49 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Mesentery: Rhabdomyosarcoma			•••••			•••••	•••••	•••••
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Nose: Adenoma	•		•••••		•••••	•••••		
7 donoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
verall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/297 (0%)	Mean 0%	SD 0%
Nose: Chondroma	•••••				•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/297 (0.34%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Nose:								
Sarcoma		0/50 (0%)	0/50 (0%) 0	)/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	` ,	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/297 (0%)	Mean 0%	SD 0%
Nose:								
Squamous Cell Carcin	oma							
		0/50 (0%)	` ,	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>-</b>	0/50 (0%)	` '	0/50 (0%)	<b>-</b>	0/49 (0%)	0/49 (0%)	0/49 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/297 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa Papilloma Squamous		nx, Tooth, Gingiva):						
	•	0/50 (0%)	( /	)/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	` '	)/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa Squamous Cell Carcin		nx, Tooth, Gingiva):					•••••	
04444110400011041041		0/50 (0%)	0/50 (0%) 1	/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	)/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa Squamous Cell Carcin Papilloma		nx, Tooth, Gingiva):			•••••			
-		0/50 (0%)		/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	` ,	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Oral Mucosa:								
Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Oral Mucosa: Squamous Cell Papilloma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
verall Incidence					Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%
·····							·····	
Ovary: Granulosa Cell Tumor Mali	gnant							
	_					0/50 (0%)	0/50 (0%)	0/50 (0%)
						1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence					Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Ovary: Granulosa Cell Tumor: Ber								
Granulosa Celi Tulliol. Dei						0/50 (0%)	0/50 (0%)	0/50 (0%)
Grandiosa Cen Tumor. Bei								
verall Incidence					Total	1/50 (2%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Route: INHALATION** Vehicle: AIR

Length of Study: CHRONIC

Male Female \*Ovary: **Granulosa-Theca Tumor Benign** 0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%) 0/50 0/50 (0%)0/50 **Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% \*Pancreas: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%) 0/50 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% 0/299 (0%) Mean 0% SD 0% Total \*Pancreas: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)(0%)0/50 (0%) 0/50 (0%)0/50 (0%)0/49 (0%) **Overall Incidence** SD 0% SD 0% Total 0/299 (0%) Mean 0% Total 0/299 Mean 0% \*Pancreas: Carcinoma or Adenoma (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** 0/299 (0%) SD 0% SD 0% Total Mean 0% Total 0/299 (0%) Mean 0% \*Pancreas: **Mixed Tumor Benign** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(4%) 0/50 (0%)2/49 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** Total 2/299 (0.67%)Mean 0.68% SD 1.67% Total 0/299 Mean 0% SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

#### **Toxicology Data Management System**

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Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups

**Route: INHALATION** Vehicle: AIR

Male Female \*Parathyroid Gland: Adenoma 0/45 (0%)0/46 0/49 (0%)0/49 (0%)0/49 (0%)0/46 (0%)(0%) 0/47 (0%)0/47 (0%)0/50 (0%)0/43 (0%)0/49 (0%)0/49 **Overall Incidence** Total 0/284 (0%) Mean 0% SD 0% 0/285 (0%) Mean 0% SD 0% Total **#Peripheral Nerve:** Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/300 (0%) Mean 0% SD 0% 0/299 (0%) Total **#Peripheral Nerve:** Schwannoma: Benign, Malignant, NOS 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** SD 0% SD 0% Total 0/299 (0%) Mean 0% Total 0/300 (0%) Mean 0% \*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma (49%)36/50 (72%)36/50 (72%)35/50 (70%)(70%)37/50 (74%)34/49 (69%)36/49 (73%)38/50 (76%) 35/50 (70%)30/50 (60%)27/49 (55%)**Overall Incidence** 215/298 (72.15%) Mean 72.14% SD 2.4% SD 9.87% Total Total 188/298 (63.09%)Mean 63.01% \*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma (0%)(0%)(0%)0/50 (0%)0/50 (0%)

1/50

(2%)

SD 0.82%

.....

0/50

1/298

Total

(0%)

(0.34%)

0/50

(0%)

Mean 0.33%

0/49

(0%)

SD 0.82%

0/50

0/49

(0%)

Mean 0.33%

Total

0/49

1/298

(0%)

(0.34%)

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Oct2007

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Pituitary Gland: Pars Dis Carcinoma or Adenom		fied Site:						
		36/50 (72%)	36/50 (72%)	35/50 (70%)		36/50 (72%)	37/50 (74%)	24/49 (49%)
		34/49 (69%)	36/49 (73%)	39/50 (78%)		35/50 (70%)	30/50 (60%)	27/49 (55%)
verall Incidence	Total	216/298 (72.48%)	Mean 72.48%	SD 3.09%	Total	189/298 (63.42%)	Mean 63.35%	SD 10.18%
Pituitary Gland: Pars Inte Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/49 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	1/298 (0.34%)	Mean 0.34%	SD 0.83%	Total	0/298 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Inte Carcinoma	ermedia:		•••••					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Inte	ermedia:	•••••	•••••					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/49 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	1/298 (0.34%)	Mean 0.34%	SD 0.83%	Total	0/298 (0%)	Mean 0%	SD 0%
Prostate: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Prostate: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)				
Overall Incidence	Total	0/299 (0%)	0/49 (0%) Mean 0%	SD 0%				
'Salivary Glands: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Salivary Glands: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b></b>	0/50 (0%)	0/49 (0%)	0/50 (0%)	<b>+</b>	0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
S	T-1-1	0/50 (0%)	0/49 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangioma						•••••		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overell Institutes	Tatal	0/50 (0%)	0/49 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>+</b>	0/50 (0%)	0/49 (0%)	0/50 (0%)	<b>.</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	T-1-1	0/50 (0%)	0/49 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma				•••••				
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Skeletal Muscle: Rhabdomyosarcoma or l	Phahdomyom	·						
Masdomy osar coma or i	Kilabaolilyolil	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Skeletal Muscle: Sarcoma					•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Normall Implication	Tatal	0/50 (0%)	0/49 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Report Date: 10/04/2007

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			Male				Female	
#Skin: Basal Cell Adenoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overell Incidence	Total	1/50 (2%)	1/49 (2%) Mean 1.01%	0/50 (0%) SD 1.1%	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
Overall Incidence	Total	3/299 (1%)	Weari 1.01%	SD 1.1%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin:								
Basal Cell Adenoma or E	Basosquamou		2/52 (22/)	2/52 (221)		0.50 (00.1)	0.70	0/50 (00/)
		1/50 (2%) 1/50 (2%)	0/50 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	3/299 (1%)	Mean 1.01%	SD 1.1%	Total	0/300 (0%)	Mean 0%	SD 0%
overall illelidelide	Total	3/299 (1/0)	Wealt 1.0170	3D 1.170	Total	0/300 (0/8)	Weatt 070	3D 070
#Skin: Basal Cell Adenoma, Bas Trichoepithelioma Overall Incidence	sosquamous Total	Tumor Benign, or  1/50 (2%)  1/50 (2%)  4/299 (1.34%)	1/50 (2%) 1/49 (2%) Mean 1.34%	0/50 (0%) 0/50 (0%) SD 1.04%	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%)	0/50 (0%) 1/50 (2%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0.82%
 #Skin:								
Basal Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma or NOS)	Basosquamo	us Tumor (malignant o	r					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
O	T-1-1	0/50 (0%)	0/49 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS

Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Skin: Basal Cell Carcinoma, Tumor (benign, malign								
rame: (semgn, mangn	u.i. 0. 1100), 0.	1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	4/299 (1.34%)	Mean 1.34%	SD 1.04%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Skin: Basal or Sq. Cell Carci								
or B), Basal Cell Adend Papilloma, Keratoacan								
. apinoma, noratoacan		5/50 (10%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	5/49 (10%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
verall Incidence	Total	15/299 (5.02%)	Mean 5.03%	SD 4.2%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
Skin: Fibroma		3/50 (6%) 4/50 (8%)	5/50 (10%) 3/49 (6%)	4/50 (8%) 2/50 (4%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	21/299 (7.02%)	Mean 7.02%	SD 2.09%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
#Skin: Fibroma, Fibrosarcoma Fibrous Histiocytoma		, ,	r					
		3/50 (6%) 5/50 (10%)	6/50 (12%) 4/49 (8%)	5/50 (10%) 3/50 (6%)		1/50 (2%) 1/50 (2%)	0/50 (0%) 2/50 (4%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	26/299 (8.7%)	4/49 (8%) Mean 8.69%	3/50 (6%) SD 2.41%	Total	1/50 (2%) 4/300 (1.33%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 1.63%
verali iliciuence	ı Uldi	20/299 (0.7%)	ivieaii 0.09%	SD 2.4170	I Ulal	4/300 (1.33%)	iviean 1.33%	3D 1.03%
Skin: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/49 (2%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	4/299 (1.34%)	Mean 1.34%	SD 1.04%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Fibrosarcoma, Sarcoma Histiocytoma	, Myxosarcom	a, or Fibrous						
		0/50 (0%) 1/50 (2%)	1/50 (2%) 1/49 (2%)	1/50 (2%) 1/50 (2%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	5/299 (1.67%)	Mean 1.67%	SD 0.82%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
#Skin: Fibrous Histiocytoma								
•		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma		0/50 (00)	0/50 (00/)	0/50 (0%)		0/50 (00/)	0/50 (00()	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma			(201)	(201)			(00)	(201)
		4/50 (8%) 1/50 (2%)	0/50 (0%) 4/49 (8%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	9/299 (3.01%)	Mean 3.03%	SD 3.99%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

(1**51011.** OCt2007

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Skin:								
Lipoma		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	2/49 (4%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	6/299 (2.01%)	Mean 2.01%	SD 1.81%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin: Liposarcoma								
p		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor						•••••		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin: Neurofibroma or Schw	annoma benign							
nour on bronna or conn	amioma bomgn	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Skin: Neurofibrosarcoma or		malignant or NOS)						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overell Incidence	Total	0/50 (0%)	1/49 (2%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups Report Date: 10/04/2007 Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Neurofibrosarcoma, Neuro malignant or NOS)	fibroma, or	Schwannoma (benign,						
,		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	` ,	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin: Osteosarcoma								
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	` /	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma						•••••		
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	` '	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	` ,	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
		0,200 (0,0)						
#Skin: Schwannoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	` ,	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/300 (0%)	Mean 0%	SD 0%
		()						

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin:								
Squamous Cell Carcinon	na	0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
		0,200 (0,0)	Moun 070					
Skin:								
Squamous Cell Carcinon	na, Basal Cell	Carcinoma,						
Basosquamous Tumor (r								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin:					•••••			
Squamous Cell Papillom	a							
Squamous Cen r apinom	а	0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin:					•••••			
Squamous Cell Papillom	a or Panillom	a						
oquamous och i upmom	a or r apmoni	0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin:								
Squamous Cell Papilloma Carcinoma or Keratoaca		Squamous Cell						
Carcinoma or Neratoacar	Illiona	4/50 (8%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	4/49 (8%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/00 (2/0)	7/70 (0/0)	1700 (270)		0/00 (0/0)	0/00 (0/0)	1/00 (2/0)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male Female #Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma 1/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)4/49 (8%)(2%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 1/300 (0.33%) **Overall Incidence** 11/299 (3.68%) Mean 3.69% SD 3.49% Mean 0.33% SD 0.82% Total Total #Skin: Trichoepithelioma 0/50 (0%)1/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%) **Overall Incidence** Total Mean 0.33% SD 0.82% 1/300 (0.33%) Mean 0.33% SD 0.82% 1/299 (0.33%)Total #Skin: Sebaceous Gland: Adenoma 1/50 (0%)(2%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)(2%)3/50 (6%) 0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** SD 2.19% SD 0% Total 6/299 (2.01%) Mean 2.01% Total 0/300 Mean 0% #Skin: Sebaceous Gland: Carcinoma (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/299 SD 0% SD 0% Total Mean 0% Total 0/300 (0%) Mean 0% #Skin: Sebaceous Gland: Carcinoma or Adenoma (2%)(0%)(2%)0/50 (0%)(0%)0/50 (0%)(2%)3/50 (6%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 6/299 (2.01%)Mean 2.01% SD 2.19% Total 0/300 Mean 0% SD 0% .....

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Spinal Cord: Astrocytoma Benign		0(50 (004)	0/50 (00/)	0/50 (00/)		0(50 (00))	0/50 (00/)	0/50 (00)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		` ,				` ,		
Spleen: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/49 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/49 (0%) SD 0%
veran incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	3D 0%
Spleen: Hemangioma			•••••			•••••		
J		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/299 (0%)	Mean 0%	SD 0%
Spleen: Hemangiosarcoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/49 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Spleen: Leiomyosarcoma	•••••							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Normall Institutes	Tatal	1/50 (2%)	0/49 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/299 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Report Date: 10/04/2007

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			Male				Female	
Stomach, Forestomach: Leiomyosarcoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Schwannoma Malignant					•••••	•••••		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>.</b>	0/50 (0%)	0/49 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma		0.70	(201)	0/50		- ()	- (	0.70
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	T-(-1	0/50 (0%)	0/49 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma c	or Papillon	na Squamous 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Papilloma			0/50 (0%/)	0/50 (09/)		0/50 (00/)	0/50 (09/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Totali ilioladiloo	iotai	3,233 (0,70)	Wicaii 070	<b>35</b> 070	iotai	3,300 (070)	Would 070	<b>3</b> D 070

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Stomach, Glandular: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	0/49 (0%) Mean 0.33%	0/50 (0%) SD 0.82%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Stomach, Glandular: Lipoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Testes: Adenoma								
		36/50 (72%)	38/50 (76%)	42/50 (84%)				
Overall Incidence	Total	33/50 (66%) 228/299 (76.25%)	38/49 (78%) Mean 76.26%	41/50 (82%) SD 6.6%				
*Thymus:	•••••	•••••						
Sarcoma		0/49 (0%)	0/48 (0%)	0/49 (0%)		0/48 (0%)	0/45 (0%)	0/47 (0%)
		0/42 (0%)	0/47 (0%)	0/49 (0%)		0/50 (0%)	0/46 (0%)	0/47 (0%)
Overall Incidence	Total	0/284 (0%)	Mean 0%	SD 0%	Total	0/283 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign								
		0/49 (0%)	0/48 (0%)	0/49 (0%)		0/48 (0%)	0/45 (0%)	0/47 (0%)
Overall Incidence	Total	()	` '	` '	Total	` ,	, ,	` '
Overall Incidence	Total	0/49 (0%) 0/42 (0%) 1/284 (0.35%)	1/47 (2%) Mean 0.35%	0/49 (0%) SD 0.87%	Total	1/50 (2%) 1/283 (0.35%)	0/46 (0%) Mean 0.33%	0/47 (0%) SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 154

			Male				Female	
Thymus: Thymoma Malignant								
Thymoma Mangham		0/49 (0%)	0/48 (0%)	0/49 (0%)		0/48 (0%)	0/45 (0%)	0/47 (0%)
		0/42 (0%)	0/47 (0%)	1/49 (2%)		0/50 (0%)	0/46 (0%)	0/47 (0%)
verall Incidence	Total	1/284 (0.35%)	Mean 0.34%	SD 0.83%	Total	0/283 (0%)	Mean 0%	SD 0%
Thymus:							•••••	
Thymoma: Benign, Maligna	ant, NOS							
		0/49 (0%)	0/48 (0%)	0/49 (0%)		0/48 (0%)	0/45 (0%)	0/47 (0%)
		0/42 (0%)	1/47 (2%)	1/49 (2%)		1/50 (2%)	0/46 (0%)	0/47 (0%)
Overall Incidence	Total	2/284 (0.7%)	Mean 0.69%	SD 1.08%	Total	1/283 (0.35%)	Mean 0.33%	SD 0.82%
Thyroid Gland: C-Cell: Adenoma								
		3/50 (6%)	2/50 (4%)	1/50 (2%)		3/50 (6%)	0/50 (0%)	3/50 (6%)
		3/49 (6%)	4/49 (8%)	7/50 (14%)		2/50 (4%)	3/50 (6%)	3/49 (6%)
Overall Incidence	Total	20/298 (6.71%)	Mean 6.71%	SD 4.14%	Total	14/299 (4.68%)	Mean 4.69%	SD 2.44%
Thyroid Gland: C-Cell: Carcinoma								
		1/50 (2%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/49 (0%)	3/49 (6%)	2/50 (4%)		1/50 (2%)	2/50 (4%)	1/49 (2%)
overall Incidence	Total	9/298 (3.02%)	Mean 3.02%	SD 2.13%	Total	6/299 (2.01%)	Mean 2.01%	SD 1.27%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		3/50 (6%)	3/50 (6%)	3/50 (6%)		3/50 (6%)	1/50 (2%)	4/50 (8%)
Sec	T-1-1	3/49 (6%)	7/49 (14%)	9/50 (18%)	Taral	3/50 (6%)	5/50 (10%)	4/49 (8%)
Overall Incidence	Total	28/298 (9.4%)	Mean 9.4%	SD 5.35%	Total	20/299 (6.69%)	Mean 6.69%	SD 2.75%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

n: Oct2007

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male	Female
Thyroid Gland: Follicular Cell: Adenoma				
		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%)
Overall Incidence	Total	0/49 (0%) 2/298 (0.67%)	1/49 (2%) 0/50 (0%) Mean 0.67% SD 1.04%	0/50 (0%) 0/50 (0%) 0/49 (0%) Total 1/299 (0.33%) Mean 0.33% SD 0.82%
		, ,		10tal 1/200 (0.0070) Wedit 0.0070 GD 0.0270
Thyroid Gland: Follicular Cell: Carcinoma				
		2/50 (4%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Warall Incidence	Total	0/49 (0%)	0/49 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/49 (0%) Total 0/299 (0%) Mean 0% SD 0%
verall Incidence	Total	4/298 (1.34%)	Mean 1.33% SD 1.63%	()
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma				
		2/50 (4%)	1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 1/50 (2%)
		0/49 (0%)	1/49 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/49 (0%)
verall Incidence	Total	6/298 (2.01%)	Mean 2.01% SD 1.27%	Total 1/299 (0.33%) Mean 0.33% SD 0.82%
Tissue NOS: Fibrosarcoma				
1 151 0001 001110		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0% SD 0%	Total 0/300 (0%) Mean 0% SD 0%
Tissue NOS: Leiomyoma				
20.0.119 01114		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0% SD 0%	Total 0/300 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**FISION.** OCI2007

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Tissue NOS: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>-</b>	0/50 (0%)	1/49 (2%)	0/50 (0%)	<b>+</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/300 (0%)	Mean 0%	SD 0%
Tissue NOS: Paraganglioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Tissue NOS: Sarcoma				•••••				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Tissue NOS: Schwannoma Malignant								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Tongue: Liposarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Normall In alidanaa	Tatal	0/50 (0%)	0/49 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Tongue:	D'''							
Squamous Cell Carcinom	ia or Papillon		4/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
S	T-1-1	0/50 (0%)	0/49 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Tongue: Squamous Cell Papilloma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
₹Tooth: Odontoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Nevall Incidence	Total	` ,	` '	0/30 (0%) SD 0%	Total	` '	` '	0/30 (0%) SD 0%
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Urinary Bladder: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%
Urinary Bladder: Carcinoma or Papilloma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	1/49 (2%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/298 (0.34%)	Mean 0.34%	SD 0.83%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: INHALATION

Report Date:10/04/2007

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Species: RATS Strain: F344

Length of Study: CHRONIC

Vehicle: AIR

			Male				Female	
*Urinary Bladder: Leiomyosarcoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	1/49 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	2/298 (0.67%)	Mean 0.67%	SD 1.04%
*Urinary Bladder: Papilloma							- 4	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
0	T-1-1	0/50 (0%)	0/49 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/49 (0%)	1/49 (2%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/298 (0.34%)	Mean 0.34%	SD 0.83%
#Uterus: Adenoma								
						0/50 (0%)	1/50 (2%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#! !to::::0:			•••••			•••••		
#Uterus: Carcinoma								
						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/300 (0%)	Mean 0%	SD 0%
#Uterus: Deciduoma Benign								
						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overell Institutes					Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/300 (0%)	Mean 0%	SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

(2%)

SD 1.1%

1/50

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)(2%) (0%)(0%)1/50 0/50 0/50 **Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Uterus: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%) 0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Uterus: Leiomyoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** SD 0% Total 0/300 Mean 0% **#Uterus: Polyp Stromal** (24%)13/50 (26%)(18%)(20%) 6/50 (12%)12/50 (24%)10/50 **Overall Incidence** (20.67%)Mean 20.67% SD 5.16% Total 62/300 **#Uterus:** Sarcoma Stromal 0/50 (0%)

.....

0/50

3/300 (1%)

Total

(0%)

0/50

(0%)

Mean 1%

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date:10/04/2007

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			Male				Female	
#Uterus: Sarcoma Stromal or Po	olyp Stromal					(222)		10/10 (000)
						14/50 (28%) 6/50 (12%)	9/50 (18%) 12/50 (24%)	13/50 (26%) 11/50 (22%)
Overall Incidence					Total	65/300 (21.67%)	Mean 21.67%	SD 5.85%
#Uterus:			•••••					
Schwannoma Malignar	nt .					0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Vagina:							•••••	•••••
Polyp						2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/50 (0%) 2/300 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.63%
#Vagina:		•••••	•••••	•••••			•••••	
Sarcoma						0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence					Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%
#Zymbal's Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

4 40 1 400

Contract/Lab: All Laboratories Species: RATS Strain: F344

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Report Date:10/04/2007

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			Male		Female
#Zymbal's Gland: Carcinoma		1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (29 0/49 (0%) 0/50 (09		1/50 (2%) 0/50 (0%) 0/50 (0%) 1/50 (2%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67% SD 1.039	% Total 3/300 (1%)	Mean 1% SD 1.1%
#Zymbal's Gland: Carcinoma or Adenoma		1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2% 0/49 (0%) 0/50 (0%	6) 1/50 (2%)	1/50 (2%) 0/50 (0%) 0/50 (0%) 1/50 (2%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67% SD 1.039	,	Mean 1% SD 1.1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied